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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,378	06/27/2000	Nick W. Warne	GI-5238BA	5593

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE 609

<b>Office Action Summary</b>	<b>Application No.</b> 09/604,378	<b>Applicant(s)</b> WARNE ET AL.	
	<b>Examiner</b> Jegatheesan Seharaseyon	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2002.
- 2a) ☐ This action is FINAL.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 and 36-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 11-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)      4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This previously abandoned Application has been revived.
2. This office action is response to Applicant's election of Group I, drawn to claims 1-35. Election was made with traverse in Paper No. 11 (2/07/02). The traversal is on the ground(s) that the search of all claims would not impose a serious burden on the Office to search both groups because both groups are classified in the same group. This is not found to be persuasive because the compositions of Group II can be used in a materially different process other than treatment of disorders, such as binding studies, antibody production and diagnostic assays. The searches for each group are not extensive and would be a burden on the Office to search all of the groups. Furthermore, it is noted that the classification system is for the convenience of the Office and is not strictly dispositive of patentable distinctness. Therefore, the restriction requirement is deemed proper and made FINAL. Claims 1-35 are pending. In addition, Applicant has further elected "mucositis (oral and gastrointestinal)". Therefore, claims 1-4 and 11-35 that read on the elected disease will be examined.

Claims 5-10 and 36-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

***Priority***

3. Applicants priority claims to applications 08/495,724 filed June 27, 1995 and 08/892,407 filed July 15, 1997 have been denied because Applicant did not contemplate using IL-11 for treating mucositis in those applications.
4. Applicant needs to update the priority information in the first paragraph of the specification with allowed patent information.

***Specification***

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite " a method of using IL-11 for treating mucositis".
6. Applicants are advised to correct the old ATCC address to the new address: ATCC, 10801 University Boulevard, Manassas, VA 20110-2209 (see page: 9, lines 20-22).

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 11-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating mucositis with IL-11, does not reasonably provide enablement for a method for treating all inflammatory disorders with IL-11. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification discloses the effect of IL-11 on treatment of mucositis (see pages 20-24 and 25-26, Examples 2 and 4). However, the claims recite, "treating an inflammatory disorder" which encompasses all conditions resulting from immune system stimulation. The instant specification is non-enabling for a method for stimulating disparate inflammatory disorders in the absence of support to accomplish a specific purpose by administration of IL-11. The recitation of the term "inflammatory disorders" in claim 1 embraces allergies, rhinitis and conjunctivitis. The ability of IL-11 to treat all disparate inflammatory disorders involving the immune system or hematopoietic system or not involving such, would not be an enabled paradigm. IL-11 could not be administered with a predictable prognosis using the specification as guidance because

the specification provides no examples nor is an enabling mechanism disclosed using IL-11 commensurate with the scope of the claims. In the absence of such a disclosure a skilled artisan would be unable to practice the methods embraced by the claims without undue experimentation.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7a. Claims 1, 11-16, 18-19, 21-27, 29-30 and 34 are rejected under U.S.C. 102(b) as being anticipated by Bennett et al. (U.S. Patent No. 5, 215,895).

The instant invention is directed to treating mucositis, an inflammatory disorder, by administering IL-11.

Bennett et al. describe a method of treating a disorder of the immune system, inflammation being an immune disorder (column 3, lines 15-18), comprising administering to a subject an amount of IL-11. Bennett et al. also teaches that IL-11 may be administered in the dosage claimed (column 11, lines 55-60). With respect to claims 1, 11-16, 18-19, 21-27, 29-30 and 34, Bennett et al teach that IL-11 can be systematically administered as an aqueous solution (column 11, lines 34-61). Therefore, Bennett et al. teach all of the process steps and material compositions of claims and therefore anticipates claims 1, 11-16, 18-19, 21-27, 29-30 and 34.

7b. Claims 1-4 and 11-35 are rejected under U.S.C. 102(b) as being anticipated by Keith et al. (1994).

The instant invention is directed to treating mucositis, an inflammatory disorder, by administering IL-11.

Keith et al. describe a method of treating mucositis an inflammatory disorder by administering to a subject an amount of IL-11 (abstract). It further teaches the amelioration of both oral and gastrointestinal mucosal damage in response to injurious stimuli (abstract). The reference also teaches the systemic administration of various dosages of IL-11 in a suitable liquid carrier (page: 80, 3rd paragraph). Therefore, Keith et al. anticipates claims 1-4, 12 and 13. Claims 11 and 14-35 are rejected insofar as they depend on rejected claims 1 and 12.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8a. Claims 1-4 and 11-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (1994) in view of Kaneko et al. in (U.S. Patent No: 4,808,613).

The instant invention is directed to treating mucositis, an inflammatory disorder, by administering IL-11.

The relevance of Keith et al. (1994) has been set forth above in paragraph 7. Keith et al. describe a method of treating mucositis an inflammatory disorder by administering to a subject an amount of IL-11. However, Keith et al. does not describe various pharmaceutical compositions of the instant invention. The reference also does not teach oral administration of the IL-11.

Kaneko et al. describe pharmaceutical compositions comprising an anti tumor agent (abstract). It describes liquid carrier including water and sodium bicarbonate (Column: 9, lines 42 - 68). It also describes compositions for oral administration containing carriers like sugars, sugar, dextrin, gelatin and cellulosic materials and the like (ibid). In addition, it further describes tablets, capsules and caplets for oral administration (ibid). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods disclosed in Keith et al. to generate the various pharmaceutical compositions for oral delivery. One of ordinary skill would have been motivated with reasonable expectation of success to modify the methods of Keith et al. because Kaneko et al.. teach pharmaceutical compositions



comprising anti-tumor agents for therapeutic purposes. Therefore, the instant invention is *prima facie* obvious over Keith et al. in view of Kaneko et al. in (U.S. Patent No: 4,808,613). Claims 11 and 14-35 are rejected insofar as they depend on rejected claims 1 and 12

8b. Claims 1-4 and 11-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (1994) and Kaneko et al. in (U.S. Patent No: 4,808,613) in view of Dandiker et al. (U.S. Patent No: 5,425,950) .

The instant invention is directed to treating mucositis an inflammatory disorder by administering IL-11.

The relevance of Keith et al. (1994) and Kaneko et al (U.S. Patent No: 4,808,613) has been set forth above in paragraph 7 and 8a respectively. Keith et al. describe a method of treating mucositis an inflammatory disorder by administering to a subject an amount of IL-11. Kaneko et al. describe pharmaceutical compositions comprising an anti-tumor agent (abstract). However, Keith et al. and Kaneko et al. references do not recite various targets for the delivery of pharmaceutical compositions of the instant invention. The reference also does not teach the sustained release of IL-11. Dandiker et al. reference teaches immediate and sustained release of compositions (column 1, lines 48-67). Dandiker et al. recite pharmaceutical compositions suitable for gastrointestinal tract, oral, rectal or vaginal administration such as tablets, suppositories and pessaries (column 3, lines 54-58). The reference also teaches formulations with enteric coating. Such coating includes cellulose acetate phthalate, polyvinyl acetate phthalate and hydroxypropyl methylcellulose phthalate. Therefore, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to modify the methods disclosed in Keith et al. and Kaneko et al. to generate the various pharmaceutical compositions for gastrointestinal tract, oral, rectal or vaginal administration. One of ordinary skill would have been motivated with reasonable expectation of success to modify the methods of Keith et al. and Kaneko et al. et al. because Dandiker et al. teach controlled release pharmaceutical compositions for therapeutic purposes. Therefore, the instant invention is *prima facie* obvious over Keith et al. and Kaneko et al. in view of Dandiker et al. (U.S. Patent No: 5,425,950). Claims 11 and 31-33 are rejected insofar as they depend on rejected claim 1.

9. No claims are allowable.

#### **Contact information**

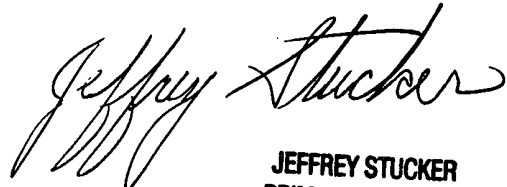
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Art Unit: 1647

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS  
December 13, 2002



JEFFREY STUCKER  
PRIMARY EXAMINER



JASEMINE C. CHAMBERS  
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